Remarks

Claims 3, 12-14 and 15 are pending in the application and stand rejected. By way of the foregoing amendment, claims 3, 12 and 13 are amended and claim 14 is canceled.

Election/Restrictions

The Examiner has withdrawn claim 14 from consideration according to the Election/Restriction issued in the August 1, 2005 Office Action. By way of this Amendment, Applicant has canceled claim 14.

Claim Rejections under 35 U.S.C. §102

The Examiner has rejected claims 3, 12 13 and 15 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Pub. No. 2002/0055575 to Torre. Torre et al. is directed to a device which is embryologically *exterior* to the body, as it is an expandable balloon for weight loss, placed within the lumen of the stomach, part of the gastro-intestinal tract, the lumen of which is embryologically exterior to the patient body, as would be understood by one of ordinary skill in the art. Attached hereto as Exhibit A is a description of the development of the digestive system which includes the stomach, the lumen of which is embryologically exterior to the patient body and thus not within the tissues of the patient body. ("Digestive System Development Neas," John F., *Embryology Atlas* , Pearson Education, Inc. 2005). The gastro-intestinal tract develops from modifications of the primitive gut that forms a continuous elongated tube from the mouth to the anus. The primitive gut develops into the gastrointestinal tract, the lumen of which is considered to be exterior to the tissues of the body.

Thus, Torre's device, embryologically *exterior* to the tissues of the body, is *exterior* to and thus not within the internal bodily tissues. Torre discloses incorporating a methylene blue dye along with the filling material placed within the

space-filling gastric device such that, upon leak or other break of the device barrier, the blue dye would enter *the lumen of the stomach* and would eventually pass into the urine stream of the patient. (*See* Torre at ¶¶[0091]-[0092].)

In contrast, the present invention is directed to a prosthesis, containing a biologically compatible chemical rupture indicator, the prosthesis, by definition, being implanted internally *within the human body tissues*. As recited by all of the pending claims, the prosthesis of the present invention has an envelope for placement internally *within the tissues of the patient body*. The biologically compatible rupture indicator, contained within the envelope, is capable of leaking out of the implant, interacting with bodily tissues (e.g. entering the vascular system) and causing a body change detectable to the patient. (*See* claims 3, 12, and 13, as amended herein). Implantation *within the tissues of the patient body* ensures interaction of the implant with tissues of the patient such that the rupture indictor may interact with internal bodily tissues, elements which are critical to the present invention. In order for the patient to be warned or signaled of rupture or impending rupture, the implant of the present invention is placed internally *within the tissues of the body* to interact with the tissues, thus allowing the rupture indicator contained therein to enact the bodily change which is later detectable to the patient, serving as the signal or warning of rupture or impending rupture.

In contrast, the intragastric device of Torre teaches placement of a device, within the lumen of the stomach, which is embryologically *exterior* to the body and thus not placed internally within the tissues of the patient body, as is requried by all elements of the present invention. Torre teaches a placement of a device at a location embryologically exterior to the body, and thus, teaches away from Applicant's present claims which require implantation internally within the tissues of the patient body.

Moreover, there is no suggestion to one of skill in the art to incorporate Torre's external methylene blue dye into Applicant's prosthesis to arrive at a rupture indicator. Specifically, there is no suggestion or motivation to incorporate a feature of an external device for placement exterior to the body tissues, into a prosthesis for implant, within the tissues of the body, in order to arrive at Applicant's rupture indicator. Additionally, Torre specifically teaches use of methylene blue dye. One of skill in the art is well aware that methylene blue is teratogenic, i.e., causing developmental malformations or fetal abnormalities, and thus that it cannot be given to or used in women of childbearing age. One of skill in the art would be taught not to use methylene blue dye disclosed of Torre within an implant to be placed internally within the tissues of a female patient. One of skill in the art would be deterred from using methyl blue dye in a breast implant, which commonly would be implanted internally within the tissues of a woman of child-bearing age, and could pose a risk to her fetus if she was or were to become pregnant while having the implant within her. Thus, there is a teaching away to one of skill in the art of using methylene blue dye, such as in Torre, and incorporating it into an implant, and particularly a breast implant, of the present invention, which is very likely to be placed internally within the tissues of a female patient of child-bearing age. Thus Applicant's claims are not disclosed or rendered obvious by Torre.

For the foregoing reasons, Applicant respectfully asserts that the present rejection of claims 3, 12, 13 and 15 has been overcome.

Conclusion

It is respectfully submitted that claims 3, 12, 13 and 15, all claims remaining in the application, are in order for allowance, and early notice to that effect is respectfully requested.

Respectfully submitted,

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